Complete Summary

GUIDELINE TITLE

Renal function testing. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Clarke W, Frost SJ, Kraus E, Ferris M, Jaar B, Wu J, Humbertson S, Dyer K, Schmith E, Gallagher K. Renal function testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 126-34. [114 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Any disease or condition requiring renal function testing including:

- Cardiovascular disease
- Renal insufficiency
- Nephritic syndrome
- Glomerular dysfunction
- Metabolic disorder
- Preeclampsia
- Renal stones
- Hemodialysis

- Intraabdominal trauma
- Renal complications of muscle injury
- Nondiabetic nephropathy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Screening

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Nephrology
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To examine the application of evidence-based medicine (EBM) to the form of diagnostic testing known as point-of-care testing (POCT)

  Note: For the purpose of this document, POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POCT refers to any testing performed outside of the traditional, core or central laboratory."

- To systematically review and synthesize the available evidence on the effectiveness of POCT, with specific focus on outcomes in the areas of:
  1. Patient/health
  2. Operational/management
  3. Economic benefit
- To address the use of POCT for renal function or urinalysis in a variety of clinical settings and patient populations

TARGET POPULATION

Patients requiring renal function testing in a variety of clinical settings such as emergency departments, hospitals, and outpatient clinics, including labor and delivery patients with preeclampsia

INTERVENTIONS AND PRACTICES CONSIDERED

Routine point-of-care testing (POCT) of blood urea nitrogen (BUN) and creatinine in the cardiovascular diagnostics laboratory

Note: 1) The following point-of-care interventions were considered and recommended against: routine measurement of blood urea nitrogen (BUN) or creatinine in the emergency department, routine screening for proteinuria with urine dipstick testing, and routine use of urine protein dipstick testing for antenatal evaluation of hypertension or preeclampsia; 2) the following point-of-care interventions were considered but no recommendations were made for or against: routine use of urine dipstick pH to screen for renal insufficiency and metabolic disorder, measurement of urine specific gravity by dipstick testing to evaluate renal function and for the assessment of urine specimen integrity, measurement of blood or urine osmolality for assessment of hydration status, dipstick testing for hematuria to evaluate the extent of glomerular dysfunction, measurement of urine or serum electrolytes, dipstick pH testing to predict renal stone recurrence, dipstick hematuria testing to detect intraabdominal trauma, measurement of lactate to assess or correct lactate buffer replacement, urine dipstick testing for myoglobinuria as an indicator for renal complications of muscle injury, and dipstick testing for microalbuminuria to assess nondiabetic nephropathy.

MAJOR OUTCOMES CONSIDERED

- Patient outcomes such as wait times, time to treatment, adverse events, length of stay
- Sensitivity, specificity, positive and negative predictive values of dipstick urinalysis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For a specific clinical use, pertinent clinical questions were formulated and key search terms were ascertained for the literature search. Searches were conducted on MEDLINE or PubMed and were supplemented with the use of the National Guideline Clearinghouse, the Cochrane Group, or evidence-based medicine (EBM) reviews. Additionally, authors' personal article collections were used. Acceptable citations were limited to peer-reviewed articles with abstracts, those published in English, and those involving human subjects.

To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Abstracts identified by the literature searches were reviewed by 2 individuals to determine initial eligibility or ineligibility for full-text review, using Form 1 (Appendix A - see the "Availability of Companion Documents" field). If there was not consensus, then a third individual reviewed the abstract(s). To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement. The systematic review consisted of creating evidence tables using Form 2 (Appendix A - see the "Availability of Companion Documents" field) that incorporated the following characteristics:

1. Study design—Prospective or retrospective, randomized, and controlled, patient inclusion/exclusion criteria, blinding, number of subjects, etc.
2. Appropriateness of controls
3. Potential for bias (consecutive or nonconsecutive enrollment)
4. Depth of method description—full-length report or technical brief
5. Clinical application—screening, diagnosis, management
6. Specific key outcomes and how they were measured
7. Conclusions are logically supported

For the assessment of study quality, the general approach to grading evidence developed by the US Preventive Services Task Force was applied (see the "Rating Scheme for the Strength of the Evidence" field). Once that was done, an assessment of study quality was performed, looking at the individual and aggregate data at 3 different levels using Forms 3 and 4 (Appendix A - see the "Availability of Companion Documents" field). At the first level, the individual study design was evaluated, as well as internal and external validity. Internal validity is the degree to which the study provides valid evidence for the populations and setting in which it was conducted. External validity is the extent to which the evidence is relevant and can be generalized to populations and conditions of other patient populations and point-of-care testing (POCT) settings.

The synthesis of the volume of literature constitutes the second level, Form 5 (Appendix A - see the "Availability of Companion Documents" field). Aggregate internal and external validity was evaluated, as well as the coherence/consistency of the body of data. How well does the evidence fit together in an understandable model of how POCT leads to improved clinical outcome? Ultimately, the weight of the evidence about the linkage of POCT to outcomes is determined by assessing the degree to which the various bodies of evidence (linkages) "fit" together. To what degree is the testing in the same population and condition in the various linkages? Is the evidence that connects POCT to outcome direct or indirect? Evidence is direct when a single linkage exists but is indirect when multiple linkages are required to reach the same conclusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The field of point-of-care testing (POCT), diagnostic testing conducted close to the site of patient care, was divided into disease- and test-specific focus areas. Groups of expert physicians, laboratorians, and diagnostic manufacturers in each focus area were assembled to conduct systematic reviews of the scientific literature and prepare guidelines based on the strength of scientific evidence linking the use of POCT to patient outcome.

Final guidelines were made according to Agency for Healthcare Research and Quality (AHRQ) classification (see the Rating Scheme for the Strength of the Recommendations field). The guidelines are evidence based and require scientific evidence that the recipients of POCT experience better health outcomes than those who did not and that the benefits are large enough to outweigh the risks. Consensus documents are not research evidence and represent guidelines for clinical practice, and inclusion of consensus documents was based on the linkages to outcomes, the reputation of the peer organization, and the consensus process used to develop the document. Health outcomes, e.g., benefit/harm, are the most significant outcomes in weighing the evidence and drafting guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

The guideline developers reviewed published cost analyses (see original guideline document for details).

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were presented in open forum at the American Association for Clinical Chemistry (AACC) Annual Meeting (Los Angeles, CA, USA) in July 2004. Portions of these guidelines were also presented at several meetings between 2003 and 2005. Participants at each meeting had the ability to discuss the merits of the guidelines and submit comments to the National Academy of Clinical Biochemistry (NACB) Web site for formal response by the NACB during the open comment period from January 2004 through October 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I—III) and grades of the recommendation (A, B, C, I) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) evidence-based practice for point-of-care testing sponsored by the NACB* have been divided into individual summaries covering disease- and test-specific areas. In addition to the current summary, the following are available:

- Chapter 1: Management
- Chapter 2: Transcutaneous Bilirubin Testing
- Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes
- Chapter 4: Coagulation

- Chapter 5: Critical care
- Chapter 6: Diagnosis and Management of Diabetes Mellitus
- Chapter 7: Drugs and Ethanol
- Chapter 8: Infectious Disease
- Chapter 9: Occult Blood
- Chapter 10: Intraoperative Parathyroid Hormone
- Chapter 11: pH Testing
- Chapter 13: Reproductive Testing

Does measurement of blood urea nitrogen (BUN) or creatinine at the point of care (vs the core laboratory) result in quicker time to treatment, decreased wait time, or decreased length of stay (LOS) for inpatient, emergency department (ED), dialysis, cardiovascular diagnostics laboratory (CVDL), or chemotherapy patients? (Literature Search 80 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 155. The guideline developers recommend against routinely providing point-of-care testing (POCT) for creatinine or BUN in the ED; they found fair evidence that POCT is ineffective in this environment.
Strength/consensus of recommendation: C
Level of evidence: II

Guideline 156. The guideline developers recommend that clinicians routinely provide POCT in the CVDL for creatinine and BUN; they found fair evidence that POCT in this environment improves important patient outcomes and that the benefits outweigh any potential harm.
Strength/consensus of recommendation: B
Level of evidence: II

Does screening for renal insufficiency by urine pH dipstick test at the point of care result in earlier diagnosis of renal insufficiency and fewer adverse events or decreased LOS for patients compared to screening by core laboratory urine pH testing? (Literature Search 81 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 157. The guideline developers are unable to recommend for or against routine use of POCT with urine pH dipstick to screen for renal insufficiency.
Strength/consensus of recommendation: I

Does screening for metabolic disorders using urine dipstick pH at the point of care result in earlier diagnosis of metabolic disorders, along with fewer adverse events and more rapid time to treatment for patients in outpatient clinics or the Neonatal Intensive Care Unit (NICU)/nursery when compared to screening by core laboratory urine pH testing? (Literature Search 82 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 158. The guideline developers are unable to recommend for or against routine use of urine dipstick pH testing for metabolic disorder screening at the point of care.
Strength/consensus of recommendation: I

Does measurement of urine specific gravity via dipstick testing at the point of care to evaluate renal function result in decreased patient wait time, quicker time to treatment, fewer adverse events, or decreased LOS for inpatient, ED, or outpatient clinic patients when compared to measurement of urine specific gravity in the core laboratory? (Literature Search 83 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 159. The guideline developers are unable to recommend for or against the routine use of urine dipsticks to measure urine specific gravity at the point of care for evaluation of renal function.
Strength/consensus of recommendation: I

Does assessment of specimen integrity by measurement of urine specific gravity by dipstick testing at the point of care result in fewer repeated patient visits because of invalid urine specimens in the ED, physician's office laboratory, or workplace drug testing setting? (Literature Search 84 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 160. The guideline developers cannot recommend for or against the routine use of urine specific gravity by dipstick testing for assessment of urine specimen integrity at the point of care.
Strength/consensus of recommendation: I

Does determination of hydration status by measurement of plasma, serum, whole blood, or urine osmolality at the point of care result in decreased patient wait time, quicker time to treatment, decreased LOS, or fewer adverse events for inpatient, ED, or outpatient clinic patients compared to measurement of osmolality in the core laboratory? (Literature Search 85 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 161. The guideline developers are unable to recommend for or against routine point of care measurement of osmolality—blood or urine—for determination of patient hydration status.
Strength/consensus of recommendation: I

Does screening for proteinuria using urine dipstick testing at the point of care to evaluate renal function result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for inpatient, ED, or outpatient clinic patients when compared to urine protein screening using a core laboratory method? (Literature Search 86 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 162. The guideline developers recommend against routinely screening for proteinuria with urine dipstick testing at the point of care; they found fair evidence that POCT screening in this environment is ineffective for improving patient outcomes.
Strength/consensus of recommendation: C
Level of evidence: II

Does detection of glomerular dysfunction by evaluation of hematuria using dipstick testing at the point of care result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for inpatient, ED, or

outpatient clinic patients when compared to evaluation of hematuria using core laboratory urinalysis? (Literature Search 87 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 163. The guideline developers are unable to recommend for or against dipstick testing for hematuria to evaluate the extent of glomerular dysfunction at the point of care.
Strength/consensus of recommendation: I

Does analysis of urine or serum electrolytes at the point of care result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for inpatient, ED, or outpatient clinic patients when compared to analysis of electrolytes using the core laboratory? (Literature Search 88 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 164. The guideline developers cannot recommend for or against measurement of urine or serum electrolytes at the point of care.
Strength/consensus of recommendation: I

Does evaluation for pregnancy-induced hypertension or preeclampsia using urine protein dipstick testing at the point of care result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for ED, outpatient clinic, or labor and delivery patients when compared to urine protein measurement using core laboratory methods? (Literature Search 89 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 165. The guideline developers recommend against routine use of urine protein dipstick testing at the point of care for antenatal evaluation of hypertension or preeclampsia; they found fair evidence that protein dipstick testing in this environment is largely ineffective.
Strength/consensus of recommendation: C
Level of evidence: II

Does the use of urine dipstick pH testing at the point of care to predict renal stone recurrence result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for inpatient, ED, or outpatient clinic patients compared to core laboratory urine pH testing? (Literature Search 90 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 166. The guideline developers are not able to recommend for or against routine use of urine dipstick pH testing at the point of care to predict renal stone recurrence.
Strength/consensus of recommendation: I

Does dipstick hematuria testing at the point of care to detect intraabdominal trauma result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for ED patients compared to evaluation of hematuria using core laboratory urinalysis? (Literature Search 91 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 167. The guideline developers are unable to recommend for or against dipstick hematuria testing at the point of care to detect intraabdominal trauma.
Strength/consensus of recommendation: I

Does measurement of lactate at the point of care to assess or correct lactate buffer replacement in hemodialysis patients result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS? (Literature Search 92 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 168. The guideline developers cannot recommend for or against measurement of lactate at the point of care to assess or correct lactate buffer replacement in hemodialysis patients.
Strength/consensus of recommendation: I

Does detection of myoglobinuria using urine dipstick testing at the point of care as an indicator for possible renal complications of muscle injury result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for inpatient, ED, and outpatient clinic patients when compared to evaluation of myoglobinuria using core laboratory urinalysis? (Literature Search 93 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 169. There is not sufficient evidence to recommend for or against urine dipstick testing for myoglobinuria at the point of care as an indicator for possible renal complications of muscle injury.
Strength/consensus of recommendation: I

Does measurement of microalbuminuria using dipstick testing at the point of care to assess nondiabetic nephropathy result in decreased wait times, reduced time to treatment, fewer adverse events, and decreased LOS for inpatient, ED, and outpatient clinic patients when compared to evaluation of microalbuminuria using core laboratory methods? (Literature Search 94 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 170. The guideline developers are unable to recommend dipstick testing for microalbuminuria at the point of care to assess nondiabetic nephropathy.
Strength/consensus of recommendation: I

Definitions:

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

It is hoped that these guidelines will be useful for those implementing new testing, as well as those reviewing the basis of current practice. These guidelines should help sort fact from conjecture when testing is applied to different patient populations and establish proven applications from off-label and alternative uses of point-of-care testing (POCT). These guidelines will also be useful in defining mechanisms for optimizing patient outcome and identify areas lacking in the current literature that are needed for future research.

POTENTIAL HARMS

Dipstick urinalysis can render false-positive or false negative results.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The material in this monograph represents the opinions of the editors and does not represent the official position of the National Academy of Clinical Biochemistry or any of the cosponsoring organizations.
- Point-of-care testing (POCT) is an expanding delivery option because of increased pressure for faster results. However, POCT should not be used as a core laboratory replacement in all patient populations without consideration of the test limitations and evaluation of the effect of a faster result on patient care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Clarke W, Frost SJ, Kraus E, Ferris M, Jaar B, Wu J, Humbertson S, Dyer K, Schmith E, Gallagher K. Renal function testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 126-34. [114 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Robert H. Christenson, Ph.D., FACB, University of Maryland School of Medicine, Baltimore, Maryland, USA; William Clarke, Ph.D., Johns Hopkins Medical Institutions, Baltimore, Maryland, USA; Ann Gronowski, Ph.D., FACB, Washington University, St. Louis, Missouri, USA; Catherine A. Hammett-Stabler, Ph.D., FACB, University of North Carolina Chapel Hill, Chapel Hill, North Carolina, USA; Ellis Jacobs, Ph.D., FACB, New York State Department of Health, Albany, New York, USA; Steve Kazmierczak, Ph.D., FACB, Oregon Health and Science University, Portland, Oregon, USA; Kent Lewandrowski, M.D., Massachusetts General Hospital, Boston, Massachusetts, USA; Christopher Price, Ph.D., FACB, University of Oxford, Oxford, UK; David Sacks, M.D., FACB, Brigham and Women's Hospital, Boston, Massachusetts, USA; Robert Sautter, Ph.D., Carolinas Medical Center, Charlotte, North Carolina, USA; Greg Shipp, M.D., Nanosphere, Northbrook, Illinois, USA; Lori Sokoll, Ph.D., FACB, Johns Hopkins Medical Institutions, Baltimore, Maryland, USA; Ian Watson, Ph.D., FACB, University Hospital Aintree, Liverpool, UK; William Winter, M.D., FACB, University of Florida, Gainesville, Florida, USA; Marcia L. Zucker, Ph.D., FACB, International Technidyne Corporation (ITC), Edison, New Jersey, USA

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Preface and introduction. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. i-xvi.
- Appendix A: NACB LMPG data abstraction forms. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 149-153.
- Appendix B: literature searches. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 154-186.

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 13, 2007. The information was verified by the guideline developer on September 24, 2007.

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